Introduction

Presented by

Larry Spears, Acting Director

Office of Compliance

Reprocessing of Single Use Devices (SUDs)

- What is it?
- Why is FDA involved?

What are the regulatory responsibilities for hospital reprocessors?

- Premarket
- Postmarket

Reuse Guidance Documents

- Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals; Final Guidance (8/14/00)
  - http://www.fda.gov/cdrh/comp/guidance/1168.pdf

Reuse Guidance Documents

- Premarket Guidance: Reprocessing and Reuse of Single-Use Devices; Draft Guidance (6/1/01)
  - http://www.fda.gov/cdrh/ode/guidance/1331.pdf

Reuse Guidance Documents

- Labeling Recommendations for Single-Use Devices Reprocessed by Third Parties and Hospitals; Final Guidance (7/30/01)
  - http://www.fda.gov/cdrh/comp/guidance/1392.pdf

Reuse Guidance Documents

- Guidance on Adverse Event Reporting for Hospitals that Reprocess Devices Intended by the Original Equipment Manufacturer for Single Use; Final Guidance (4/24/01)
  - http://www.fda.gov/cdrh/osb/guidance/1334.pdf

Reuse Website

- http://www.fda.gov/cdrh/reuse/index.shtml